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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,991	11/20/2001	Gregory Luedtke	219002029100	1704

25225 7590 07/08/2004  
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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/989,991

### Applicant(s)

LUEDTKE ET AL.

### Examiner

Celia Chang

### Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,3-7,9,12,39-43,45,46,48-50,52-61 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 64-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,57,58,60,63 and 68 is/are rejected.
- 7) ☐ Claim(s) 3-7,9,12,39-43,45,46,48-56 and 59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

1. This application is a RCE of SN 09/989,991. The after final amendment dated Feb. 5, 2004 have been entered per request of filing this RCE. Claims 2, 8, 10, 11, 13-38, 44, 47, 51 and 62 have been canceled. Claims 64-67 stayed withdrawn being drawn to the nonelected invention. Claims 1-9, 12, 39-61, 63, 68 are pending.

2. The new issue or new matter encompassed by the entry of the above after final amendment have been communicated to applicants in the advisory action and hereby incorporated as the following:

The newly inserted terms "heteroalkyl", "heteroalkenyl", "heteroalkynyl" or "[hetero]forms thereof containing 1-2 O,S and/or N" are ambiguous and indefinite (claims 1, 57,

58, 60). It is unclear what structure are these terms defining. Is this  $\begin{array}{c} \text{O} \\ | \\ -\text{C}-\text{Me} \end{array}$  heteroalkyl or is this  $-\text{C}-\text{O}-\text{alkyl}$  heteroalkyl? The first scenario is chemically named alkylcarbonyl, while the second scenario is chemically named alkoxyalkyl. Although applicants can act as his or her own

lexicographer to specifically define a term of a claim, but such definition must be consistent with the common understanding to one skilled in the art. As it was delineated supra, it is unclear what does each term define and how do those terms be related to the chemical structure commonly known to one skilled in the art.

The terms "...can be joined to form a [fused].....aromatic or nonaromatic, saturated or unsaturated ring which contains 3-8 members..." in several moieties are indefinite and unclear. It is unclear what does it mean when two substituents join or two "R" join, or two noninterfering substituents with R join into rings. Please note that although functional language can be employed to define requirement, the instant situation the definition of such "chemical structure" to render a scope defining the inclusiveness or noninclusiveness of a compound to be covered by the claim is very confusing. Please note that the picking and selecting of such structure is defined on page five is "to be determined by assays for determining the ability of an compound to inhibit p38- $\alpha$  activity". Not only such activity can vary based on which assay one chooses but also the determination of this "structural" requirement is literally can only be made *after* the

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compound has been made and tested. Therefore, it is undue for one skilled in the art to know which compound is within the scope of the claim and which is not. The issues about size and structure has been clearly explained in Paper no. 12 and 14 (04/04/03 and 10/06/03) and hereby incorporated by reference.

Further, the claims encompassed composition and method for treating conditions mediated by p38- $\alpha$  activity (claims 63 and 68). Please note that treating a condition mediated by p38- $\alpha$  activity does not necessarily meeting the utility requirement since p38- $\alpha$  activity, if not producing any pathology in a person, as mere alleviation of p38- $\alpha$  activity has no utility. Further, while compounds treating certain pathology/disease through the p38- $\alpha$  activity mechanism does not warrant a scope for treating all p38- $\alpha$  activity involved conditions. It is noted that p38- $\alpha$  activity is one activity of the cytokines (see p.1 specification) which has been known to be specific for the particularly tested disease but no extrapolation can be predicted due to the high degree of unpredictability (see CA 125:3127).

The same new issue and new matter rejection has been made on *some* of the terms used in the previous amendments which are applicable with respect to the instant amendments also are hereby incorporated by reference (applicants should consult the rejections of Paper No. 14 dated Oct. 6, 2003).

3. Dependent claims 3-7, 9, 12, 39-43, 45-46 48-50, 52-56, 59, 61 are objected to as being dependent upon a rejected base claim, but would be allowable when all the 112 issues of the base claims have been resolved or if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. This is a RCE of applicant's earlier Application No. 09/898,001. All claims are drawn to the same invention claimed in the earlier application and the 112 issues with respect to the new issue and new matter have been conveyed to applicants in paper no. 14 and the advisory action and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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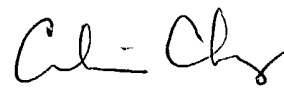
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
July 6, 2004

  
Celia Chang  
Primary Examiner  
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